Debate

NEAR-PATIENT TESTING

Near-patient testing will improve the control of sexually transmitted infections: the arguments in favour

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The development of near-patient testing in the sexual health field in recent years provides a much needed opportunity to improve the control of sexually transmitted infections (STIs). However, in many fields, this opportunity to improve sexual health is not being fully realised.

Sexual health has deteriorated markedly over the past decade. Diagnoses of the most common STIs have risen markedly,[1] with these increases almost certainly caused at least partly by changes in behaviour and by worsening service access.

An increasing body of social and behavioural research suggest that more people are having sex with more partners at an earlier age. It is a trend that needs to be better reflected in the UK's sexual health service response.[2]

With such changes in the behaviour and increase in diagnoses of STI, it is not surprising that services have struggled to manage. Less than half of all people seeking treatment in genito urinary medicine (GUM) clinics of the National Health Service (NHS) are seen within 48 h, with 25% of people having to wait more than 2 weeks.[3]

Furthermore, worsening service access may, in itself, be helping to fuel increasing levels of STIs. In broad terms, a vicious circle may be emerging in which worsening sexual health causes longer waits for GUM services, and these prolonged waiting times in turn facilitate further increases in transmission and diagnosis of STI.

This state of affairs is particularly worrying because of the UK's hitherto strong track record in the sexual health field. There is a strong heritage of high-quality public health surveillance and GUM service delivery, as well as a strong track record of response to HIV in the 1980s and 1990s.

DEVELOPING A FRESH RESPONSE

Such is the scale of growth, and the scale of behaviour change that new ways of responding to these pressures are needed. These fresh approaches need to include developing managed service networks so that the access can be increased while ensuring robust clinical governance arrangements are in place, redesigning services so that the care pathway can be simplified and made quicker and easier for use by patients, and introducing new ways of diagnosing and preventing STIs by making best use of new diagnostic technologies and by linking these with strengthened work on sexual health promotion.

STI diagnostic technology has developed markedly over the past decade. Increasingly, diagnostic tests that make use of fingerstick capillary blood specimens or urine sampling, and that can be used in less traditional settings are becoming available. Furthermore, tests that make minimal use of laboratory facilities, and that can give patients and clinicians a result more rapidly than in the past are becoming available.

This technology is still not perfect in many areas, but it is contributing to improved individual and public health where it is available. A case in point is the availability of fingerstick capillary blood specimen HIV screening tests, which can be undertaken in non-specialist settings, with results available within 15 min, and positive results being followed up with a confirmatory venepuncture.

Technological advances have enabled the continued development of point-of-care testing (POCT). The use of POCT presents many challenges for sexual health services. It begins to call into question existing approaches to service delivery—for example, fingerstick testing for HIV raises questions about conventional approaches to counselling before and after testing. It also raises questions about individual professional roles in sexual health teams—for example, the availability of a POCT for *Chlamydia* would open up the possibility for skilled community workers to administer the test, freeing nursing staff to take on a greater clinical leadership role, and a greater role in the management of complex cases, and in the prescription of drug treatment. It also raises the future spectre of test kits being used with no or minimal professional supervision, which would have an effect on the way in which contact tracing and surveillance work is undertaken. Taken together, there is also potentially a longer-term, and arguably beneficial, consequence of putting patients in greater control of their own sexual health and care.

These challenges may seem daunting; however, they should not be allowed to come in the way of maximising the use of POCT where appropriate. There are at least six reasons for this.

Improving standards

POCT can play an important part in helping services maintain and improve standards. Despite the herculean efforts of doctors, nurses and health advisers, many services have seen access erode[4 5] under the weight of demand. This is as frustrating for those providing the service as it is for those waiting to be treated.

A vicious circle has developed of increasing demand, reduced access to clinics, and increased incidence of STIs leading to further demands on services, and this must be broken. Now of course, there are those who argue that all that is needed

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is extra investment, and that with £300 million being made available to improve sexual health services in 2006–7 and 2007–8, in England at least this vicious circle is about to be broken. However, a fog of gloom and despair is slowly descending over many English services, as it becomes increasingly clear that much of this promised investment may not reach its destination, with sexual health being sacrificed on the altar of Primary Care Test financial balance.

In these circumstances, POCT could have an important role in helping establish a virtuous circle, which, if used correctly, enables a reduction in the number of people with straightforward needs requiring GUM care, thereby leading to the achievement of access targets, a more prompt diagnosis and a reduction in the level of infection. Linked with the appropriate use of Patient Group Directions expanding access to treatment, this could be a powerful force in helping improve access standards.

Economic benefits

POCT can make strong economic sense. By not being dependent on existing professionally undertaken tests, less use needs to be made of specialist clinical services for routine clinical activity. Already, fingerstick HIV tests potentially allow most of the people who test negative when taking an HIV test to be seen away from a GUM clinic. As testing technology improves, the potential for this service approach being routinely applied to other STIs will increase.

The effect of this in clinics could be marked, allowing valuable clinical expertise to focus on those people in greatest need, and allowing funders to increase the health utility of their expenditure in sexual health services. This will be particularly important in those fields where services are groaning under the pressure of underfunded increases in demand.

Beyond this, if POCT enables more people to access an STI test at an earlier time, the NHS may be able to prevent some of the costs associated with undiagnosed *Chlamydia* and HIV.[6]

In time further economic benefits could accrue if the more widespread availability of POCT enabled test kits to be sold over the counter. This would allow part of the financial burden of diagnosing STIs to be shifted from the public to the private purse for those who choose to buy a test and test themselves. It would of course be important to prevent a two-tier service emerging by ensuring that all services funded by the NHS remain open to all who wish to use them.

Empowering patients

POCT provides an important way of empowering patients to take greater responsibility for their own sexual health. It does so by expanding the settings where STI testing can be undertaken, thereby allowing people to exercise greater choice over where, when and how they access the services. Linked to evidence-based health promotion programmes, this could achieve a step change in patient empowerment. The Terrence Higgins Trust has long highlighted the effect of stigma on patient empowerment in sexual health, and POCT, by giving people a larger say in their own care, is an important means of dealing with this.[7]

Improving health

POCT can enable a more rapid improvement in health. By enabling earlier diagnosis, POCT can provide earlier access to treatment and support, with correspondingly faster relief of symptoms.

Such an improvement in individual health would in turn be likely to lead to an improvement in public health. Earlier diagnosis of STI coupled with effective treatment reduces the infectivity period, thereby minimising the likelihood of ongoing transmission. Indeed, in recent years, commentators have suggested that there are public health benefits of using existing suboptimal POCT to enable rapid treatment of people with *Chlamydia* who have large numbers of sexual partners, where there is a notable risk of onward transmission.[8 9]

Tackling health inequality

POCT provides an important means of dealing with the effect of health inequality on poor sexual health. It is well recognised that young people, homosexual men, sex workers and some black/minority ethnic communities experience the worst sexual health. Many of these communities are often mislabelled as being ''hard to reach'' when in fact it is the services that are hard to reach. Indeed, it is no understatement to say that a hard-to-reach sex worker is an unemployed sex worker! POCT, by enabling the greater use of STI testing in local community settings, allows services to be more easily accessed by people with health inequalities.

The benefits of POCT in these circumstances may exist even with current suboptimal tests. Vickerman *et al*[9] in 2003 calculated that a gonorrhoea POCT test kit would only need 47% sensitivity to show a health benefit among sex workers in the UK.

Patient choice and preference

Although POCT in its infancy, it is becoming increasingly available, and is already proving popular with some patient groups. A clear example is the early adoption of HIV tests sold over the internet by some homosexual men. This is of concern, as some of these test kits are of highly questionable reliability, have sparse product/health information and offer little in the way of support for people who receive a positive result.

This popularity is backed by the early findings from a review of the ''Fastest'' HIV testing clinics run by Terrence Higgins Trust in partnership with several GUM services. The use of 15-min rapid result tests in these clinics has proved popular with both homosexual men and black and minority ethnic communities using them. If this is the case for a serious condition such as HIV, it almost certainly will be the case for more easily treated STIs.

Although understandable, the reluctance may be in some GUM services to embrace this technology, it is surely better that people have the choice of a local supervised rapid-access POCT than that they are left with no option but to wait for venepuncture or use the internet.

Debate

CHALLENGING THE ARGUMENTS AGAINST NEAR-PATIENT TESTING

Many arguments are often ranged against POCTs. The most common is that the lack of accuracy of the tests largely renders them redundant for the time being. This requires careful examination, as it is an assertion that is often made. Several HIV POCTs are currently available, offering levels of sensitivity between 96.7% and 100%.[10] Indeed, the levels of sensitivity are such that at least one of the POCTs is beginning to be used in an increasing number of GUM clinics. In addition, anti-HCV and hepatitis B surface antigen POCTs with adequate sensitivity and specificity for use in groups at high risk are also achievable now.[11 12]

A review of rapid syphilis diagnostics carried out by the World Health Organisation in 2003 concluded that in settings with a high prevalence, all six POCTs evaluated ''showed excellent overall performance compared to the reference standard tests''. It also concluded that ''in areas of low disease prevalence, it may be possible to use these as screening tests''. It would almost certainly be necessary for positive results to be confirmed by a second, different test; however, this does suggest that in UK populations at high risk for syphilis, there may be merit in the use of a syphilis POCT for screening work.[13]

Clearly, this does not mean that similarly sensitive tests can easily be developed for other STIs; however, it does illustrate the pace of technological progress, and increases the likelihood of the benefits of technological advance being felt in other parts of the STI field in the future.

It also asks the question regarding the level of specificity and sensitivity, which is needed to ensure effectiveness. For example, several *Chlamydia* POCTs are currently available, with sensitivities of between 60% and 70%. An inner-city US study published in 2004 suggested that *Chlamydia* POCTs of such sensitivities can play an important part in populations where there is a marked risk of people being lost to follow-up and therefore not receiving treatment. It also suggested that the effect could be even higher if combined with other approaches to treatment of STI.[14]

Another important factor in considering sensitivity is the initial time taken to access a test. This is particularly pertinent in the UK, where only half of GUM services currently enable people to be seen within 48 h, with some having much longer waits. Even where clinics are making progress in achieving the target, evidence suggests that many people may still find it difficult to get an appointment.[15] As such, the longer the wait, the greater the potential utility of a POCT even if it does have a lower sensitivity than a gold standard nucleic acid amplification test.

Other arguments that are used against POCTs include the potential implications for contact tracing and the implications for surveillance, particularly if such tests are to used without clinical supervision. Although these issues are serious, they should not be showstoppers; rather they represent challenges to be faced as a result of advances in technology.

Indeed, new approaches to contact tracing are already needed as a result of the rapid growth in diagnoses of STI in recent years. A key objective in this must be to give the patient a more empowered role to self-contact trace. Similarly, work is already taking place nationally to ensure that surveillance mechanisms are developed in response to changes in the patterns of service delivery. Both of these provide an opportunity to deal with the additional issues raised by POCT. More to the point, no one can surely argue that POCT should not be pursued because of the effect on contact tracing and surveillance—surely the priority has to be the diagnosis and treatment of infection.

CONCLUSION

It is not a case of whether near-patient testing will improve STI control, but rather how we ensure that it does. The pace of technological change over the past decade strongly suggests that in the next decade, near-patient testing will become an accepted part of the sexual health mainstream. The challenge for all of us in the sexual health field is how to maximise the utility of this technological advance to improve the sexual health of the nation.

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